General

Guideline Title

Management of gynecologic issues in women with breast cancer.

Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Management of gynecologic issues in women with breast cancer. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2012 Mar. 17 p. (ACOG practice bulletin; no. 126). [166 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendation and conclusion is based on good and consistent scientific evidence (Level A):

- Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) have both been shown to be safe and to reduce the severity of hot flushes in patients with breast cancer, although caution must be used when using these agents in conjunction with tamoxifen. Gabapentin and clonidine are other options for management of hot flushes.

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- The 2009 National Comprehensive Cancer Network Task Force report recommends that pharmacologic therapy should be considered for women with breast cancer who have T scores between -1.5 and -2.0.
- Routine endometrial biopsy and uterine ultrasonography are not recommended for postmenopausal women taking tamoxifen without bleeding.
- Contraceptive options for patients with breast cancer include barrier methods, such as condoms and diaphragms, the copper intrauterine device, and sterilization.
- Pregnancy after breast cancer is not thought to increase breast cancer recurrence.
- If future pregnancy is desired for women in whom breast cancer has been diagnosed, appropriate consultation with fertility specialists should be offered to ascertain whether immediate assisted reproductive strategies are possible to preserve fertility.

The following recommendation is based primarily on consensus and expert opinion (Level C):

- Nonhormonal methods should be considered first-line treatment for vaginal atrophy in women with a history of hormone-sensitive breast

cancer.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Gynecologic health issues related to breast cancer and breast cancer treatment, including menopausal symptoms, infertility, sexual function, contraceptive issues, and osteoporosis

Guideline Category

Evaluation

Management

Prevention

Risk Assessment

Treatment

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Obstetrics and Gynecology

Oncology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To review the effect of breast cancer treatment on common women's health issues such as fertility, contraceptive management, menopause, sexual function, and osteoporosis
- To provide a rationale for follow-up and treatment of these gynecologic issues

Target Population

Women who have or have had breast cancer

Interventions and Practices Considered

1. Osteoporosis risk assessment (clinical risk factors and bone marrow density testing and monitoring)
2. Bisphosphonates and raloxifene for osteoporosis prevention and treatment
3. Counseling about lifestyle changes to reduce the risk of bone loss and osteoporotic fractures
4. Selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), gabapentin, and clonidine for vasomotor symptoms
5. Use of nonhormonal methods for treatment of vaginal atrophy
6. Routine endometrial biopsy and uterine ultrasonography (not recommended for postmenopausal women taking tamoxifen without bleeding)
7. Contraceptive options: barrier methods, such as condoms and diaphragms, the copper intrauterine device, and sterilization
8. Avoidance of hormones for contraception
9. Counseling on fertility and infertility, including potentially fertility-preserving options

Major Outcomes Considered

- Rate of breast cancer treatment-related gynecologic adverse effects
- Effectiveness of management strategies for treatment-related adverse effects

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between June 2010 and November 2011. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Level C

recommendations.

Rating Scheme for the Strength of the Recommendations

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of gynecologic health issues in women treated for breast cancer

Potential Harms

Bisphosphonates

Very rare adverse effects associated with the long-term use of bisphosphonates have been suggested but not yet confirmed, including atypical femur fractures and osteonecrosis of the jaw. Although generally well tolerated, the adverse effects of raloxifene include vasomotor symptoms (hot flushes and night sweats) and an increased risk of thromboembolic events.

Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)

The optimal balance between effectiveness and adverse effects of venlafaxine (most commonly, dry mouth, nausea, constipation, and poor appetite) appears to be a dose of 75 mg, with larger doses associated with an increased likelihood of adverse effects with no further clinical

benefit.

There is some significant concern that the use of pure SSRIs in women taking tamoxifen may interfere with tamoxifen metabolism and thus block the drug's therapeutic benefit. This interference with tamoxifen appears to be less severe or nonexistent for SNRIs such as venlafaxine.

Gabapentin

Adverse effects, including dizziness, are common.

Ultrasound Surveillance

In women taking tamoxifen, ultrasound surveillance has been associated with a significant false-positive rate because tamoxifen induces enlargement of the subendometrial glands, resulting in increased endometrial thickness, irregular echoes, and cystic changes; but, these findings do not correlate with malignant histology. In general, endometrial thickness alone should not be used as an indicator for intervention because it will lead to unnecessary invasive diagnostic procedures.

Ovarian Stimulation for In Vitro Fertilization (IVF) Procedures

One of the concerns with immediate IVF with embryo cryopreservation is whether the high levels of estrogen produced by ovarian stimulation will have adverse effects on breast cell proliferation. In the general infertility population, there are no convincing data that ovulation induction or IVF increases the risk of breast cancer. It is not known if the high estrogen milieu has any adverse effect on breast cancer that is already established.

Contraindications

Contraindications

- It is relatively contraindicated to use hormonal contraceptive options in patients with breast cancer.
- The use of hormone therapy is generally contraindicated in patients with hormone-positive breast cancer.
- Some oncologists have felt that conventional ovulatory stimulating agents are contraindicated; therefore, patients with breast cancer have previously been offered unstimulated or natural-cycle IVF, which has results in patients without cancer that may approach IVF pregnancy rates.

Qualifying Statements

Qualifying Statements

The information in this guideline is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Mar

Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins—Gynecology

Composition of Group That Authored the Guideline

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the

Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site .

Availability of Companion Documents

A proposed performance measure is included in the original guideline document.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 3, 2012.

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